**Non-Confidential Summary of Safety and Effectiveness**
Page 1 of 3
8-May-08

MAR 6 2009

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Tel – 905-677-9410

**Official Contact:** Ammar Al-Dojaily

**Proprietary or Trade Name:** CAREvent PAR

**Common/Usual Name:** ventilator, emergency, powered (resuscitator)

**Classification Name:** ventilator, emergency, powered (resuscitator)
BTL – 868.5925

**Predicate Devices:** O-Two Medical - CAREvent BSL+ - K991195
Auralogic - CPR Coach voice prompter – K860555

**Device Description:**

The CAREvent PAR® is an electronically controlled, pneumatically powered resuscitator with a 12V, internal, rechargeable battery is used to power the electronics. It incorporated voice instructions to assist the user during CPR.

**Indications for Use:**
The CAREvent PAR (Public Access Resuscitator) is indicated for Cardio Pulmonary Resuscitation (CPR) and short –term ventilatory support. It incorporates voice instructions, compression beeps and automatic ventilations to assist CPR Trained personnel for both inter – and intra-hospital transport and pre-hospital (EMS) settings for non-breathing adult patients.

**Patient Population:**
Non-breathing adult patients

**Environment of Use:**
Hospitals (inter - and intra- transport), pre-hospital (EMS) settings

**Contraindications:**
None

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8-May-08

**Comparative table:**

| Features | Predicates<br>K991195 – CAREvent BLS+<br>K860555 – CPR Coach voice prompter | Proposed Device<br>CAREvent PAR |
|---|---|---|
| **Indications for use** | Pulmonary resuscitation during respiratory and / or cardiac arrest. Short-term ventilatory support for both inter- and intra-hospital transport of non-breathing patients (K991195)<br><br>No indications for use statement but states voice prompts for CPR (K860555) | The CAREvent PAR (Public Access Resuscitator) is indicated for Cardio Pulmonary Resuscitation (CPR) and short – term ventilatory support. It incorporates voice instructions, compression beeps and automatic ventilations to assist CPR Trained personnel for both inter – and intra-hospital transport and pre-hospital (EMS) settings for non-breathing adult patients. |
| **Environment of Use** | inter- and intra-hospital transport (K991195) | Same added pre-hospital as this is covered under inter-hospital transport |
| **Patient Population** | Non-breathing adult and child (K991195) | Non-breathing adults |
| **Contraindications** | None (K991195) | None |
| **Software driven** | No (K991195)<br>Yes K860555 | Yes, some features – Respiratory rate (BPM), Pressure relief audible alarm, voice prompts |
| **Components uses** | Controller – multi-patient, multi-use Circuit and mask – single patient use disposable (K991195) | Same |
| **Components** | Ventilator / controller<br>Circuit<br>Mask<br>Head strap (K991195) | Ventilator / controller<br>Circuit<br>Mask<br>Head strap |
| **Instructional voice prompts** | Yes (K860555) | Yes |
| **Performance and design features** | | |
| **Can deliver 100% oxygen during resuscitation** | Yes (K991195) | Yes |
| **Tidal volume (l)** | 12 settings (L) 1.35, 1.1, 0.9, 0.8, **0.7**, 0.6, 0.5, 0.4, 0.35, 0.3, 0.25, 0.2 (K991195) | Fixed – 0.7 |
| **Respiratory Rate (BPM)** | 12 settings 10, 12, 15, 18, **20** (K991195) | Fixed - 20 |
| **I:E ratio** | Fixed 1:2 (K991195) | Fixed 1:2 |

**Non-Confidential Summary of Safety and Effectiveness**
Page 2 of 3
8-May-08

| Features | Predicates<br>K991195 – CAREvent BLS+<br>K860555 – CPR Coach voice prompter | Proposed Device<br>CAREvent PAR |
|---|---|---|
| **Maximum Pressure relief (cm H2O)** | 60<br>(K991195) | 60 |
| **Pressure relief audible alarm** | Yes<br>(K991195) | Yes |
| **Manual ventilation option** | Yes<br>(K991195) | No |
| **Demand breathing feature** | No<br>(K991195) | No |
| **Circuit pressure** | 40 psi<br>(K991195) | Same |
| **Input gas pressure** | 45-70 psi<br>(K991195) | Same |
| **Input fitting/ Output fitting** | 9/16 DISS<br>22mm | Same |

**Differences Between Other Legally Marketed Predicate Devices:**

The proposed device is viewed as substantially equivalent to the predicate devices, K991195 and K860555.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

O-Two Medical Technologies, Incorporated
C/0 Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

MAR 6 2009

Re: K081330
Trade/Device Name: CAREvent PAR
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: February 23, 2009
Received: February 24, 2009

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement



**510(k) Number:** _____ (To be assigned)

**Device Name:** CARE*vent* PAR

**Indications for Use:** The CARE*vent* PAR (Public Access Resuscitator) is indicated for Cardio Pulmonary Resuscitation (CPR) and short –term ventilatory support. It incorporates voice instructions, compression beeps and automatic ventilations to assist CPR Trained personnel for both inter – and intra-hospital transport and pre-hospital (EMS) settings for non-breathing adult patients.

**Prescription Use XX** (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081330